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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,926	12/31/2001	Yocheved Hagay	10793/50	9603
26646	7590	06/17/2005	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			BLANCHARD, DAVID J	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 06/17/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,926

Applicant(s)

HAGAY ET AL.

Examiner

David J. Blanchard

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21 and 42-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 42-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/28/2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Claims 1-20 and 22-41 have been cancelled.
Claim 21 has been amended.
Claims 42-56 have been added.
2. Claims 21 and 42-56 are pending and under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. This Office Action contains New Grounds of Rejection.

Objections/Rejections Withdrawn

5. The substitute sequence listing has been entered.
6. The objection to the oath/declaration as containing non-initialed alterations is withdrawn in view of the declaration filed 3/22/2005.
7. The objection to the abstract for exceeding 150 words is withdrawn in view of the abstract filed 3/22/2005.
8. The rejections of claim 21 (parts a-d) under 35 U.S.C. 112, second paragraph, as being indefinite are withdrawn in view of the amendments to the claim.

Response to Arguments

9. The rejection of claims 21 and applied to newly added claims 42-56 under 35 U.S.C. 112 first paragraph because the specification does not enable any person skilled

in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with the claims is maintained.

The response filed 3/22/2005 has been carefully considered, but is deemed not to be persuasive. The response states that the claim amendments define the heavy chain variable region as comprising a CDR3, CDR2, and CDR1 having SEQ ID NO:8, 115 and 114, respectively, which renders the rejection moot. In response to this argument, it is reiterated that while being enabling for a scFv and dsFv wherein the variable heavy chain comprises CDR3, CDR2, CDR1 having SEQ ID NOS:8, 115, 114, respectively, and wherein the scFv and dsFv binds glycolalicin or svFvs consisting of SEQ ID NO:25, 208 and 235 wherein the scFvs bind glycolalicin, does not reasonably provide enablement for a scFv and dsFv wherein the variable heavy chain comprises CDR3, CDR2, CDR1 having SEQ ID NOS:8, 115, 114, respectively, or svFvs consisting of SEQ ID NO:25, 208 and 235, wherein the antibodies do not have a binding function or bind an antigen other than glycolalicin. The specification discloses only a Y1 antibody comprising a heavy chain comprising CDR3, CDR2 and CDR1 having SEQ ID NOS:8, 115, 114, respectively, that binds glycolalicin expressed by target cells (see "The ORF of Y1-IgG-HC" at pages 94-95 and pages 89-91). The specification also discloses that the scFvs of SEQ ID NO:208 and 235 bind glycolalicin. The specification discloses at paragraph 130 the scFv consisting of SEQ ID NO:25, however, it is unclear what antigen specificity this antibody has. The specification does not provide any guidance or direction with respect to the claimed antibodies that do not bind antigen or bind an antigen different from glycolalicin and one skilled in the art would not know how

to use antibodies that do not bind antigen as encompassed by the claims. The claims do not recite any functional language with respect to antigen specificity. Amending the claims to recite the antigen specificity of the claimed antibodies would overcome this rejection.

10. The provisional rejection of claim 21 and applied to newly added claims 42-51 under the judicially created doctrine of obviousness type double-patenting as being unpatentable over claim 29 and newly added claims 119 and 140 of copending Application No. 10/029,988 is maintained.

The response filed 3/22/2005 has been carefully considered, but is deemed not to be persuasive. The response states that since no claims have yet been allowed, this rejection is not timely and should be withdrawn. In response to this argument, applicant is reminded that the rejection is a provisional rejection since the conflicting claims have not in fact been patented and as such the rejection is timely and proper. The response also states that once the co-pending application issues, if necessary at that time, a terminal disclaimer will be filed in the appropriate application. In response to this argument, not terminal disclaimer has been filed and the rejection is maintained.

New Grounds of Objection/Rejection

11. The disclosure is objected to because "Ali" in Table 10 is misspelled.

Appropriate correction is required.

12. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 recites the limitation "the scFv". There is insufficient antecedent basis for this limitation in the claim. Claim 42 from which claim 52 depends does not recite a scFv.

13. Claims 52 and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The response filed 3/22/2005 has introduced NEW MATTER into the claims. Newly added claims 52 recites that the polypeptide consisting of SEQ ID NO:8 (CDR3) and SEQ ID NO:115 (CDR2) and SEQ ID NO:114 (CDR1) further comprises a light chain variable region consisting of SEQ ID NO:7. Applicant pointed to paragraphs 129 and 186 for support, however, support for a scFv consisting of the heavy chain CDRS of SEQ ID Nos:8, 115 and 114 and a light chain consisting of SEQ ID NO:7 cannot be found. Paragraphs 129 and 186 do not contemplate this antibody molecule. Newly added claim 56 recites a scFv consisting of SEQ ID NO:235. Paragraphs 129 and 186 as-filed do not support a scFv consisting of SEQ ID NO:235. Newly added claims 52 and 56 now recite limitations, which were not clearly disclosed in the specification as

filed, and now change the scope of the instant disclosure as filed. Such limitations recited in newly added claims 52 and 56, which did not appear in the specification, as-filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in present claim 54 in the specification or claims, as-filed, or remove these limitations from the claims in response to this Office Action.

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1642

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
6/10/05